Policy principles on the supply of medicines in Ireland outside formal reimbursement

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1. Context: Early Access for patients to innovative medicines

IPHA member companies are committed to improving people's health through the development and provision of innovative medicines and technologies. They wish to make new medicines available to patients as soon as possible, collaborating with their doctors and other health care professionals to support the best available care and treatment.

After new medicines are authorised (licensed) by the European Commission or the Health Products Regulatory Authority in Ireland, IPHA members usually apply to the Health Service Executive (HSE) for payment (reimbursement). They prepare and engage fully in the complex value and other assessment processes set by the HSE. They seek fair agreements on price and terms and conditions of reimbursement, using the IPHA Framework Agreement with the State.

While this process is underway, and in some circumstances even before authorisation, doctors sometimes ask for the medicine concerned to be made available for an unmet medical need of a patient in their care.

Under European[1] and Irish legislation, medicines must be authorised before being marketed. In Ireland, there are two authorisation exemptions that are relevant for the treatment of patient conditions where there are medical needs that cannot be met by authorised medicines.

These are:
(i) Supply through participation in an approved clinical trial; or
(ii) In accordance with the specifications of a doctor for use by his individual patients on his/her direct personal responsibility, to fulfil the needs of those patients.

Currently, the legislative basis to supply medicines for specific groups of patients with an unmet medical need is Article 5 of Directive 2001/83/EC. Such supply schemes may be referred to within companies as 'Early access programmes,' 'compassionate use programmes' and 'named patient programmes' that are usually initiated at the request of a doctor.

IPHA member companies thus contribute to advancing the standard of care for patients and supporting doctors by making new medicines available in these circumstances.

[1] Article 83 of Regulation 726/2004 defines specific conditions under which a medicine, which has not yet been authorised, may be supplied for the treatment of patients where no alternative authorised medicine is available for treatment of the following medical conditions: 1) Chronic disease 2) Seriously debilitating disease and 3)Life threatening disease. The medicine concerned must also be either the subject of an application for a marketing authorisation under Regulation 726/2004 or undergoing clinical trials.

1. Application of the principles

The following policy principles are set out to articulate IPHA's agreed best practices to members and stakeholders.

For members, they are intended to act as general guidance for the common position of IPHA. They do not form part of the IPHA Code of Practice for the Pharmaceutical Industry, adherence to which is mandatory for IPHA members, and member companies are responsible for their internal policies in this area.

For our stakeholders, they explain the approach and principles agreed by IPHA member companies in relation to the supply of medicines outside the context of pricing and reimbursement approval.

2. Type of supply in scope

These principles cover the supply of medicines prior to a pricing and reimbursement decision by the HSE, usually but not exclusively, after the receipt of a marketing authorisation. It is intended to apply to medicines which are intended by the company to be on the HSE's reimbursement list. It excludes medicines provided as part of a clinical trial and medicines supplied by the Executive under Section 23 of the Health Act (Pricing and Supply of Medical Goods).

3. Publication and updating

These principles have been adopted by the IPHA Prescription Medicines Division Strategy Board and may be updated from time to time. They will be published on the IPHA website, www.ipha.ie.

Principles to consider regarding the Supply of Medicines outside of Reimbursement

1. Within legal requirements, medicines may be supplied by companies outside of formal pricing and reimbursement approval by the HSE. This may be in response to a specific request by a doctor to address an unmet medical need of their patient. Companies follow internal procedures in assessing and deciding upon such requests. They are generally overseen by doctors and/or may form part of a set programme scheme with specific conditions for supply in these circumstances.

2. In all cases, companies must ensure compliance with the relevant regulations in relation to the supply of unauthorised medicines and free of charge medicines. They must also ensure that the appropriate risk management and pharmacovigilance measures associated with the medicine are followed.

3. No company is under any obligation by virtue of these principles to supply any medicine outside of the pricing and reimbursement process.

4. Companies must practice transparency and predictability with those doctors and other relevant stakeholders in relation to the supply of medicines outside of the pricing and reimbursement process.

5. Transparency and predictability require that companies must explain the conditions relating to the supply of the medicine concerned to doctors who have made a request for a medicine. These can include and are not limited to: patient eligibility/suitability criteria; the start/stop conditions related to the supply of the medicines in the above programmes and/or schemes and any limits to the extent or duration of supply.

6. A clear distinction must be outlined upfront to the doctor between 1) the ending of a programme/ scheme of supply for new patients, and 2) any potential for, or risk to, the ending of the supply to an existing patient. The latter should be discussed directly with the treating doctor where the best interest of the patient(s) concerned receive central consideration and any change **should** be made in agreement with the treating doctor.

7. The supply of a medicine outside of the pricing and reimbursement process, or any conditions of such supply, must not be prejudicially used by companies in applications to, or negotiations with, the HSE for advancement within the pricing and reimbursement process of that medicine. Companies expect also that the HSE will not leverage such 'supply outside reimbursement' in its considerations and/or negotiations regarding that same medicine(s) for reimbursement.

8. Where the reimbursement of a medicine is agreed by the HSE, companies may have a reasonable expectation that all supply would proceed on a reimbursed basis, including any supply previously made without reimbursement, for the reimbursed indication(s). However, where a HSE Managed Access Protocol or prescribing guidelines for the medicine are put in place, this expectation will be confined to the terms of that protocol or those guidelines. The continuation of supply for patients outside the HSE Managed Access Programme must be managed in accordance with principles in paragraphs 5 and 6 above.

9. For the absence of doubt, where companies supply medicines 'free of charge,' they make no representation about the absence of other potential charges by other agents in the pharmaceutical supply chain.